Can we do resect and discard with AI-assisted colon polyp 'optical biopsy'?

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Abstract:

Resect and discard refers to a paradigm for the management of colorectal adenomas 1-5 mm in size. In this paradigm, histology of colorectal polyps is predicted endoscopically based on surface features. Lesions that are ≤ 5 mm in size and predicted to be adenomas are resected endoscopically and discarded rather than submitted to pathology. Adenomas in this size range have an extremely low risk of cancer, and the cost savings of the resect and discard paradigm would be substantial. Artificial intelligence programs can improve the overall prediction for histology based on endoscopic imaging and reduce operator dependence in endoscopic predictions. Although meta-analyses have concluded that the accuracy of endoscopic prediction is sufficiently high to institute the resect and discard paradigm in clinical practice, actual implementation has faced several obstacles. These include lack of financial

incentives for endoscopists, perceived increased medical-legal risk compared to the current management paradigm of submitting all polyps to pathology, and local rules for tissue handling.

Keywords: colonoscopy; artificial intelligence; colorectal polyp; adenoma; hyperplastic polyp

Introduction: What is resect and discard?

Resect and discard is a proposal for a new paradigm for management of diminutive colorectal polyps encountered during colonoscopy (1). The current paradigm is to remove all diminutive polyps encountered, except when there are multiple hyperplastic appearing lesions in the rectosigmoid. In that instance, the usual care is to sample a few of the hyperplastic lesions, or to leave all of them in place. In the resect and discard paradigm, diminutive colorectal polyps are first assessed endoscopically to predict their histology. Diminutive lesions that appear both benign and adenomatous, are then resected and disposed of rather than submitted to pathology.

The resect and discard paradigm depends on the ability of endoscopists to predict diminutive colorectal polyp histology accurately. This process generally involves the application of an endoscopic classification scheme for histology. The most commonly used and discussed scheme in clinical practice is the Narrow Band Imaging International Colorectal Endoscopic classification (NICE) which was developed for use in high definition non-magnifying Olympus colonoscopes and narrow band imaging (2) (Table 1). Although the NICE classification was developed for use with Olympus narrow band imaging (NBI), it has been successfully applied using colonoscopes made by other Japanese manufacturers, and their respective alternative electronic chromoendoscopy formats. Recently, a system

analogous to NICE has been developed specifically for use with Fujinon colonoscopes and the blue light imaging (BLI) modality (3). The endoscopic appearance of (BLI) is qualitatively very similar to NBI, as is the BASIC classification (BLI Adenoma Serrated International Classification). The Kudo classification was developed for use in magnifying colonoscopes with chromoendoscopy (4). Although the structures described in the NICE and BASIC classifications may not be precisely the same as those described in the Kudo classification, it is widely accepted that lesions of the NICE type 1 correspond to Kudo types I and II, and the lesions of the NICE 2 variety (adenomas) represent the Kudo III and IV classes. Nice type 3, which is indicative of deep submucosal invasive cancer (5), corresponds to Kudo V.

The NICE 1 classification represents both the hyperplastic polyps and the sessile serrated polyps (also called sessile serrated adenomas and sessile serrated lesions). The NICE classification does not attempt to distinguish hyperplastic polyps (HPs) from sessile serrated polyps (SSPs), but it does make note that large open pits are a feature of sessile serrated polyps. The WASP classification (Working Group on Serrated Polyps) combines both surface details and gross morphologic features to distinguish hyperplastic polyps from sessile serrated polyps (6)(Table 2). The success with which the WASP classification can be applied to diminutive NICE type 1 lesions to distinguish hyperplastic polyp from sessile serrated polyp is currently unclear.

The resect and discard paradigm was formalized in 2011 by an American Society for Gastrointestinal Endoscopy (ASGE) PIVI (Preservation and Incorporation of Valuable Endoscopic Innovation) (1). The PIVI proposed that resect and discard an appropriate paradigm for the management of diminutive colorectal polyps if the application of resect and discard in clinical studies, followed by assignment of

colonoscopy surveillance intervals based on endoscopic histologic predictions, corresponded with surveillance intervals based entirely on pathology in ≥ 90% of cases. The PIVI included both the resect and discard policy and a second policy in which a strategy was proposed to leave distal diminutive polyps in place with increased confidence in their hyperplastic pathology. In the latter policy, if the negative predictive value of endoscopic predictions for adenomas in the rectosigmoid was > 90%, then leaving these lesions in place was considered appropriate therapy. In clinical studies, achieving the resect and discard target has been somewhat more difficult than achieving the 90% threshold for negative predictive value for adenomas among diminutive rectosigmoid lesions (7).

As a consequence of limited ability of endoscopic prediction to assign NICE type 1 lesions as hyperplastic versus sessile serrated polyps, the resect and discard policy has been basically proposed to affect diminutive conventional adenomas throughout the colon. In this management paradigm, lesions predicted to be diminutive colorectal conventional adenomas anywhere in the colon could be documented by photography, resected, and discarded. Proximal to the sigmoid colon, NICE 1 lesions would be resected and submitted to pathology so that they could be accurately classified as HP versus SSP. For type 1 lesions in the rectosigmoid, they can be reasonably left in place. In a recent study, less than 2% of diminutive NICE type 1 lesions in the rectosigmoid were found to be SSPs by experienced pathologists (8).

The risks of the resect and discard paradigm include the potential of an endoscopist to resect a diminutive cancer and discard it rather than submit it to pathology. Recent analyses suggest that the risk of this event is extremely low and in one large recent series, there were no cancers among > 30,000 diminutive colorectal polyps (9). The decline in the prevalence of cancers seen in recent studies may

reflect the very large numbers of extremely flat lesions detected with modern high definition colonoscopes. The second risk is inaccurate assignment of surveillance intervals after colonoscopy. It is now widely held that failure to detect lesions is of considerably more importance for the development of interval cancer than is misclassification of surveillance intervals (10, 11). Surveillance intervals are both widely overused and underused in clinical practice (12, 13). Thus, the critical element to prevent interval cancers is high adenoma detection rates (ADRs) (10, 11). Current guidelines suggest that the group with 1 or 2 adenomas < 10 mm in size can undergo colonoscopic surveillance at either 5 or 10 years (14). Since patients with normal colonoscopies are advised to undergo repeat screening colonoscopy at 10 years, the use of surveillance intervals of 10 years means that resect and discard is considerably less likely to create errors when policies follow the 10-year interval for 1 or 2 adenomas < 10 mm in size. That group (1-2 adenomas less than 10 mm in size) constitutes about two thirds of the entire adenoma bearing cohort (15). A third obstacle is the challenge of measuring the ADR if lesions are not submitted to pathology. ADR has emerged as the most important quality predictor in colonoscopy, and measurement rests on pathologic identification of conventional adenomas. However, about 15% of adenomas 1-3 mm in size removed and submitted to pathology are called normal by pathologists (16). This almost certainly results from failure to section the actual polyp tissue versus normal tissue around the polyp that was resected and submitted with the specimen, or fragmentation of the polyp during retrieval (17). Thus, current ADR measurements already underestimate ADR. A recent study found that photography could be used to accurately support ADR measures (18). Under the resect and discard policy, the record of an adenoma is a photograph that captures the features on which the prediction of adenoma was made, rather than a glass slide in the pathology department.

The benefit of resect and discard is primarily cost reduction. One cost analysis suggested a proposed savings of over $1 billion per year in the U.S. alone by the resect and discard proposal (19). Another more conservative cost analysis suggested a savings of $33 million (20).

Evidence for resect and discard from clinical studies

A large number of clinical studies have assessed the predictive value of endoscopic classification schemes for differentiating conventional adenomas from serrated class lesions (21-23), and applied these to determination of surveillance intervals. Meta-analyses conducted by independent groups (23), and by the technology assessment committee of the ASGE (24), have determined that narrow band imaging has been effectively used to reach both of the PIVI criteria, supporting the institution of the PIVI paradigms in clinical practice. One feature seen in some of the available literature is that endoscopic experts tend to outperform community-based endoscopists in their predictions of histology (7, 22, 23).

Obstacles to resect and discard

The resect and discard policy is seldom implemented in clinical practice at the present time. This is true despite the development of a substantial amount of supportive evidence. This paradox reflects the reality that in order for a new medical management paradigm to move forward, the paradigm may require more than supportive evidence. Table 3 lists a number of factors that affect the acceptance of new management paradigms. In some cases, these factors can be more or much more important than the evidence supporting the paradigm. The first important factor affecting acceptance is whether some involved factions have reduced income as a result of the new paradigm. An excellent example of where

this factor determined the implementation of a new paradigm is endoscopist directed propofol for endoscopic procedures. The evidence that endoscopists could safely supervise the administration of propofol, and that the practice was cost effective, was overwhelming (25). Despite that, the anesthesia community effectively blocked implementation of endoscopist directed propofol, and arguably because of concerns over loss of income (26). In the case of resect and discard, potentially adversely affected factions include pathology as a specialty and endoscopists who own pathology laboratories. However, neither of these groups seems to be as politically powerful as the anesthesiology and nurse anesthetist communities, though they might block implementation of resect and discard at the national, state, or institutional levels. Furthermore, endoscopists implementing resect and discard in a fee for service model have no apparent financial incentive to perform endoscopic predictions. Although society in general and insurance companies in particular could benefit from resect and discard financially, there is no financial reward in the U.S. for endoscopic prediction of histology. In Japan, this conundrum was solved by a national policy reimbursing endoscopists for the use of image enhanced endoscopy (IEE). Most experts agree that the prospects for reimbursement for IEE in the U.S. are low.

A second important factor that can determine the outcome of a proposed paradigm is the associated or perceived medical-legal risk associated with a new paradigm. Here again the analogy with endoscopist directed propofol is apparent, since the administration of propofol provided no financial advantage to endoscopists and produced significant perceived and probably real medical-legal risk for endoscopists administering propofol. Similarly, many endoscopists perceive an increased medicolegal risk in the resect and discard policy. If a patient developed an interval cancer, an expert might opine that the resected lesion was a cancer, even though it is much more likely that the interval cancer arose from a separate missed lesion. In this regard, photography of each resected lesion would appear to provide

protection for endoscopists, but the actual outcome of medical legal actions seems potentially unpredictable.

Due to these factors, the use of IEE for the specific purpose of resect and discard is not a U.S. Food and Drug Administration (FDA) approved indication for these technologies. Indeed, the FDA, which takes positions largely based on patient safety or perceptions of safety, seems unlikely to approve any technology that moves patients from the current paradigm toward one that is perceived as having increased risk, regardless of proposed cost savings. Additional questions for endoscopists include: how do I become trained in IEE? Do I need to have training in IEE to utilize resect and discard? Do I need to become credentialed in IEE? Do I need to establish an institutional policy regarding resect and discard? Do I need to establish a quality program for monitoring the accuracy of endoscopic predictions in resect and discard? For all these reasons, and given the lack of a financial incentive to utilize resect and discard, it is easy to understand why the paradigm has made little progress. One solution for decreasing medical legal risk would be to video record all colonoscopic procedures, a policy that is becoming increasingly feasible and affordable.

Artificial intelligence and resect and discard

Obviously, image analysis has enormous potential for artificial intelligence (AI). Indeed, AI programs have already shown substantial accuracy for differentiating conventional adenomas from NICE type I lesion (27-38). Training deep learning programs to differentiate hyperplastic polyp from sessile serrated polyp is complicated by the high interobserver variation between pathologists in making this differentiation, which adds challenges for developing an effective AI program.

One very valuable aspect of AI predictions of diminutive colorectal polyp histology would be to eliminate the skill variability previously noted between academic expert endoscopists and community based endoscopists (7, 23). However, as noted above, this discrepancy in skill level in endoscopic interpretation is only part of the layer of obstacles arrayed against the resect and discard paradigm. However, AI would increase accuracy, improve documentation, and provide a support tool for endoscopists' predictions. Again, for legal reasons, AI is likely to be considered an adjunct to predicting histology, analogous to the development of narrow band imaging as an adjunct to gastrointestinal imaging.

Summary and conclusions

The evidence that resect and discard can be effectively applied to conventional adenomas throughout the colorectum during colonoscopy is already present, particularly for expert endoscopists. Artificial intelligence holds the promise of reducing previously observed differences between expert endoscopists and other endoscopists in achieving accurate endoscopic prediction. AI would also improve documentation and serve as a useful support tool for endoscopists' prediction of histology. Of course, AI will serve as an important adjunctive imaging tool for a variety of endoscopic decisions that are based on image enhanced endoscopy that go beyond resect and discard. However, the ultimate emergence of the resect and discard paradigm, which from the perspective of logic and effective use of resources seems inevitable, will depend on other factors such as changes in reimbursement structure and development of effective medical-legal protections.

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Table 1. NICE classification

	Type 1	Type 2	Type 3
Color	Same or lighter than background	Browner relative to background (verify color arises from vessels)	Brown to dark brown relative to background; sometimes patchy whiter areas
Vessels	None, or isolated lacy vessels may be present coursing across the lesion	Thick brown vessels surrounding white structures†	Has area(s) with markedly distorted or missing vessels
Surface pattern	Dark spots surrounded by white	Oval, tubular, or branched white structures† surrounded by brown vessels	Distortion or absence of pattern
Most likely pathology	Hyperplastic or sessile serrated polyp (SSP)	Adenoma	Deep submucosal invasive cancer

†structures may represent the pits and epithelium of the crypt opening.

Table 2. Features of SSPs in the WASP classification

Large open pits
Indiscrete borders
Irregular surface
Cloud-like appearance

SSP: Sessile serrated polyp

WASP: Workgroup on serrated polypS and Polyposis

Table 3. Factors determining forward movement of new medical paradigms

Evidence to support the paradigm
Cost-effectiveness of the new paradigm relative to the established paradigm
Financial incentives and disincentives for specialties involved in the new and old paradigms
Political influence of involved parties
Perceived medical-legal risk in new versus old paradigms
National, state, and institutional rules affecting the new paradigm

Abbreviations

NICE - Narrow Band Imaging International Colorectal Endoscopic

NBI - narrow band imaging

BLI - blue light imaging

BASIC - BLI Adenoma Serrated International Classification

WASP - Workgroup serrAted polypS and Polyposis

ASGE - American Society for Gastrointestinal Endoscopy

PIVI - Preservation and Incorporation of Valuable endoscopic Innovation

HP - hyperplastic polyp

SSP - sessile serrated polyp

mm - millimeter

ADR - adenoma detection rate

IEE - image enhanced endoscopy

U.S. FDA - United States Food and Drug Administration

AI- artificial intelligence